# **Complete Summary**

### **GUIDELINE TITLE**

ASGE guideline: the role of endoscopy in the management of variceal hemorrhage, updated July 2005.

## **BIBLIOGRAPHIC SOURCE(S)**

Qureshi W, Adler DG, Davila R, Egan J, Hirota W, Leighton J, Rajan E, Fanelli R, Wheeler-Harbaugh J, Baron TH, Faigel DO, Standards of Practice Committee. ASGE Guideline: the role of endoscopy in the management of variceal hemorrhage, updated July 2005. Gastrointest Endosc 2005 Nov;62(5):651-5. [65 references] PubMed

### **GUIDELINE STATUS**

This is the current release of the guideline.

# **COMPLETE SUMMARY CONTENT**

**SCOPE** 

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS EVIDENCE SUPPORTING THE RECOMMENDATIONS BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS QUALIFYING STATEMENTS IMPLEMENTATION OF THE GUIDELINE INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT **CATEGORIES** IDENTIFYING INFORMATION AND AVAILABILITY **DISCLAIMER** 

### SCOPE

## **DISEASE/CONDITION(S)**

Variceal hemorrhage from esophageal or gastric varices

## **GUIDELINE CATEGORY**

Diagnosis Management Prevention Screening Treatment

### **CLINICAL SPECIALTY**

Gastroenterology

#### **INTENDED USERS**

Physicians

## **GUIDELINE OBJECTIVE(S)**

To provide an updated, practical strategy for the specific use of endoscopy in screening for esophageal varices, prevention of the initial bleeding, and the management of patients with variceal hemorrhage

### **TARGET POPULATION**

- Patients with variceal hemorrhage (management)
- Patients with liver cirrhosis and portal hypertension (screening)

### INTERVENTIONS AND PRACTICES CONSIDERED

### Screening

Esophagogastroduodenoscopy (EGD)

### Management

- 1. Primary prophylaxis
  - Beta-blockers (propranolol or nadolol)
  - Endoscopic sclerotherapy (EST) (considered but not recommended for primary prophylaxis)
  - Endoscopic variceal ligation (EVL) (reserved mostly for patients who cannot tolerate or have contraindications to beta-blockers)
- 2. Endoscopic treatment for variceal hemorrhage
  - Endoscopic variceal ligation (EVL)
  - Endoscopic sclerotherapy (for patient who fail EVL)
  - Endoscopic therapy using cyanoacrylate compounds or sclerotherapy (for gastric varices)
- 3. Concomitant beta-blocker therapy
- 4. Antibiotic prophylaxis to prevent infectious complications of EVL and EST
- 5. Follow-up EGD surveillance at regular intervals

### **MAJOR OUTCOMES CONSIDERED**

- Mortality and morbidity
- Rate of growth of varices
- Rates of first variceal hemorrhage
- Complications of endoscopic treatments for variceal hemorrhage
- Recurrent bleeding
- Time to variceal obliteration

### **METHODOLOGY**

# METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Searches of Electronic Databases

### **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

A MEDLINE literature search was performed, and additional references were obtained from the bibliographies of the identified articles and from the recommendations of expert consultants. When inadequate data existed from well-designed prospective trials, emphasis was given to results from large series and reports from recognized experts.

### NUMBER OF SOURCE DOCUMENTS

Not stated

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

**Expert Consensus** 

### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

### METHODS USED TO ANALYZE THE EVIDENCE

Review

Review of Published Meta-Analyses

### **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

Not stated

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

**Expert Consensus** 

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Guidelines for appropriate utilization of endoscopy are based on a critical review of the available data and expert consensus.

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

### **COST ANALYSIS**

A formal cost analysis was not performed and published cost analyses were not reviewed.

### METHOD OF GUIDELINE VALIDATION

Not stated

### **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

Not applicable

## **RECOMMENDATIONS**

### **MAJOR RECOMMENDATIONS**

Recommendations are followed by evidence grades (A-C) identifying the type of supporting evidence. Definitions of the evidence grades are presented at the end of the "Major Recommendations" field.

# **Screening For Esophageal Varices**

Effective prophylactic treatments to prevent variceal bleeding exist for patients with esophageal varices. There are no reliable methods of predicting which cirrhotic patients will have esophageal varices without endoscopy. An American Association for the Study of Liver Diseases guideline suggests that patients with Child's stage A liver cirrhosis and signs of portal hypertension, specifically a platelet count of less than 140,000/mm<sup>3</sup>, and/or enlarged portal vein diameter of greater that 13 mm or those classified as Child's B or C at diagnosis should have screening endoscopy. Patients with cholestatic disease may have portal hypertension with relatively preserved liver function and platelet counts. A retrospective study of 235 patients concluded that patients with either primary biliary cirrhosis or primary sclerosing cholangitis who have a platelet count <200/mm<sup>3</sup>, an albumin level <40 gm/L, and a bilirubin level >20 micromoles/L should be screened for esophageal varices. Other groups recommend screening for all patients diagnosed with cirrhosis. The optimal surveillance intervals for esophageal varices have not been determined. For patients found to have no varices on initial screening endoscopy, repeat endoscopy at 3-year intervals has been suggested, whereas patients with small varices should undergo endoscopy in 1 to 2 years. Esophageal varices may grow faster in patients with cirrhosis secondary to alcohol abuse or severe liver impairment and in those with endoscopic stigmata of high risk ("red wale markings"); this subgroup of patients should undergo yearly upper endoscopy.

# **Primary Prophylaxis**

Because of the high mortality rate associated with the initial variceal hemorrhage, primary prevention is indicated. Non-selective beta-blockers (e.g., propranolol or nadolol), given in doses to reduce the pulse rate by 25%, have been shown to prevent or delay the first episode of variceal bleeding. Early beta-blocker therapy may slow the rate of growth of small esophageal varices.

Endoscopic sclerotherapy (EST) is not recommended for primary prophylaxis.

In most cases, it is recommended that prophylactic endoscopic variceal ligation (EVL) be reserved for patients who cannot tolerate or have contraindications to beta-blocker use, or in those who do not show a reduction in hepatic vein pressure gradient (HVPG) of >20% or <12 mm Hg.

## **Endoscopic Treatments For Variceal Hemorrhage**

## **Endoscopic Variceal Ligation (EVL)**

EVL has become the treatment of choice both for controlling variceal hemorrhage and for variceal obliteration in secondary prophylaxis.

In contrast to EST, EVL appears to rarely induce bacteremia. Although antibiotic prophylaxis is indicated for all patients hospitalized for variceal bleeding, the decision to use antibiotic prophylaxis in high-risk patients solely to prevent the infectious complications of EVL should be individualized. Recurrence of esophageal varices may develop more frequently in those treated with EVL, and regular endoscopic surveillance remains a critical aspect of management. EVL may be more difficult to use than EST in the presence of active bleeding because of poor visibility or operator inexperience. The introduction of multiple-band firing devices has made EVL more widely acceptable and it is favored by many over EST for eradication of esophageal varices. Concomitant treatment with a beta-blocker should be considered as this has been reported to further decrease the rate of rebleeding from 38% to 14% (p = 0.006). The combination of EST and EVL does not appear to be better than EVL alone.

### **Endoscopic Sclerotherapy (EST)**

EST is successful in controlling active bleeding in over 90% of patients and can reduce the frequency and severity of recurrent variceal hemorrhage. Gastric varices in continuity with esophageal varices may be treated with EST below the esophagogastric junction. Isolated gastric varices are less amenable to EST. Sclerotherapy may be performed by intravariceal or paravariceal injection of a sclerosant. Several agents (sodium tetradecyl sulfate, sodium morrhuate, ethanolamine oleate, polidocanol, and ethanol) have been used at varying concentrations, volumes, and treatment intervals. More frequent treatments achieve more rapid variceal obliteration than less frequent treatments, but are associated with greater mucosal ulceration.

Patients with a mechanical prosthetic cardiac valve, a history of endocarditis, a surgically created systemic pulmonary shunt, or a synthetic vascular graft (placed within the previous year) should receive antibiotic prophylaxis before the

procedure. In patients with ascites, antibiotic prophylaxis should also be considered.

### **Gastric Varices**

Gastric varices are most commonly located in the cardia in continuity with esophageal varices. Isolated gastric varices are most commonly located in the fundus and can be seen in patients with cirrhosis and portal hypertension, as well as in patients with splenic vein thrombosis (e.g., from pancreatic disease) or portal vein thrombosis. Bleeding from gastric varices is typically high volume in nature and can present with massive hematemesis.

In general, endoscopic therapy for the treatment of bleeding gastric varices has been less successful than for esophageal varices. Treatment options that have been studied in prospective trials include injection of cyanoacrylate-based tissue adhesives, alcohol, sclerosants, and the use of band ligation. Results from this limited number of small studies have had varying success rates and were uncontrolled, making it difficult to draw definitive conclusions about their efficacy or the superiority of one therapy over another. All techniques appear to be useful, but rebleeding and mortality rates in these studies were high. There are insufficient data to recommend repeat endoscopic procedures to achieve obliteration or secondary prophylaxis of isolated gastric varices.

Cyanoacrylate-based compounds have not been approved by the Food and Drug Administration for use in the US. Injection of cyanoacrylate-based compounds is associated with the development of bacteremia, and thus antibiotic prophylaxis should be considered in high-risk patients.

# Summary of Recommendations for the Use of Endoscopy in the Management of Variceal Hemorrhage

	Clinical Situation	Management	
No prior variceal bleeding			
Established cirrhosis, especially in patients with platelet counts <140,000/mm³, or Child's class B or C disease	Perform screening esophagogastroduodenoscopy (EGD)	Large varices/endoscopic stigmata: treat with beta-blocker; perform EVL if patient is intolerant or has contraindications to beta-blocker use Small varices: repeat EGD every 1-2 years No varices: repeat EGD every 3 years	
Current or prior variceal bleeding from esophageal varices			
Perform EVL	Repeat every 2-4 weeks until varices are eradicated: perform EST if EVL fails; consider betablocker use	Following eradication: perform EGD every 6-12 months; repeat EVL (or EST) if varices recur	
Current variceal bleeding from gastric varices			
Attempt endoscopic the with or without detach	nerapy using cyanoacrylate compour	nds, sclerotherapy, or EVL	

	Clinical Situation	Management	
Primary or secondary prophylaxis of gastric varices			
Insufficient data to rec	ommend endoscopic therapy		

### **Summary**

- Bleeding from esophageal or gastric varices is a common cause of morbidity and mortality in patients with portal hypertension (B).
- Patients with cirrhosis and portal hypertension but no prior variceal hemorrhage (especially those with platelet counts <140,000/mm³, or Child's Class B or C) should undergo screening EGD (B) and treatment with a betablocker if large varices are found (A).
- EVL is effective for primary prophylaxis (A), but in most cases it should be reserved for patients who cannot tolerate or who have contraindications to beta-blocker therapy (C).
- Patients with small varices on screening EGD should undergo a repeat procedure every 1 or 2 years, and those without varices should repeat the EGD every 3 years (C).
- In patients with current or prior bleeding from esophageal varices, EVL is the preferred endoscopic treatment and is superior to EST (A).
- Following an episode of bleeding from esophageal varices, EVL should be performed every 2 to 4 weeks until the varices are eradicated (C). Concomitant beta-blocker therapy should be considered (A).
- Following variceal eradication, EGD should be repeated every 6 to 12 months and recurrent varices should be treated with EVL (C).
- EST should be reserved for patients who fail EVL (C).
- Although endoscopic therapy for actively bleeding isolated gastric varices may be effective, there are insufficient data to recommend a specific type of endoscopic treatment in this setting (C).
- There are not sufficient data to recommend endoscopy for obliteration or as primary or secondary prophylaxis of isolated gastric varices (C).

## **Definitions**:

- A. Prospective controlled trials
- B. Observational studies
- C. Expert opinion

# **CLINICAL ALGORITHM(S)**

None provided

## **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and classified for the recommendations using the following scheme:

A. Prospective controlled trials

- B. Observational studies
- C. Expert opinion

When little or no data exist from well-designed prospective trials, emphasis is given to results from large series and reports from recognized experts. Guidelines for appropriate utilization of endoscopy are based on a critical review of the available data and expert consensus.

# BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### **POTENTIAL BENEFITS**

Appropriate use of endoscopy in screening for esophageal varices, in the prevention of initial bleeding, and in the management of patients with variceal hemorrhage

### **POTENTIAL HARMS**

- Complications of endoscopic sclerotherapy (EST) include fever, retrosternal discomfort or pain, dysphagia, injection-induced bleeding, esophageal ulceration with delayed bleeding, esophageal perforation, mediastinitis, pleural effusion, bronchoesophageal fistula, adult respiratory distress syndrome, and infectious complications.
- Endoscopic variceal ligation (EVL) may be more difficult to use than EST in the presence of active bleeding because of poor visibility or operator inexperience.
- Injection of cyanoacrylate-based compounds is associated with the development of bacteremia.

# **QUALIFYING STATEMENTS**

### **QUALIFYING STATEMENTS**

Further controlled clinical studies are needed to clarify aspects of this statement, and revision may be necessary as new data appear. Clinical consideration may justify a course of action at variance to these recommendations.

## **IMPLEMENTATION OF THE GUIDELINE**

# **DESCRIPTION OF IMPLEMENTATION STRATEGY**

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

## **IOM CARE NEED**

Getting Better Living with Illness Staying Healthy

### **IOM DOMAIN**

Effectiveness

# **IDENTIFYING INFORMATION AND AVAILABILITY**

## **BIBLIOGRAPHIC SOURCE(S)**

Qureshi W, Adler DG, Davila R, Egan J, Hirota W, Leighton J, Rajan E, Fanelli R, Wheeler-Harbaugh J, Baron TH, Faigel DO, Standards of Practice Committee. ASGE Guideline: the role of endoscopy in the management of variceal hemorrhage, updated July 2005. Gastrointest Endosc 2005 Nov;62(5):651-5. [65 references] PubMed

### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

### **DATE RELEASED**

2005 Nov

## **GUIDELINE DEVELOPER(S)**

American Society for Gastrointestinal Endoscopy - Medical Specialty Society

### **SOURCE(S) OF FUNDING**

American Society for Gastrointestinal Endoscopy

### **GUIDELINE COMMITTEE**

Standards of Practice Committee

### COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Douglas O. Faigel, MD (Chair); Todd H. Baron, MD (Vice Chair); Waqar Qureshi, MD; Douglas G. Adler, MD; Raquel Davila, MD; James Egan, MD; William Hirota, MD; Jonathan Leighton, MD; Elizabeth Rajan, MD; Robert Fanelli, MD (SAGES Representative); Jo Wheeler-Harbaugh, RN (SAGES Representative)

### FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

### **GUIDELINE STATUS**

This is the current release of the guideline.

### **GUIDELINE AVAILABILITY**

Electronic copies: Available in Portable Document Format (PDF) from the American Society for Gastrointestinal Endoscopy (ASGE) Web site.

Print copies: Available from the American Society for Gastrointestinal Endoscopy, 1520 Kensington Road, Suite 202, Oak Brook, IL 60523

### **AVAILABILITY OF COMPANION DOCUMENTS**

None available

### **PATIENT RESOURCES**

None available

### **NGC STATUS**

This NGC summary was completed by ECRI on December 7, 2005. The information was verified by the guideline developer on December 14, 2005.

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